DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95690d

VIA CERTIFIED MAIL

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

WARNING LETTER

FLA-03-05

October 16, 2002

M. Sue Smyrnios, President and Owner
Steinhatchee Fish Inc.
D/b/a Steinhatchee Fish Company
105 First Avenue S.W.
Steinhatchee, Florida 32359

Dear Mrs. Smyrnios:

We inspected your firm, located at 105 First Avenue S.W., Steinhatchee, Florida on May 7-9, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your cooked, ready-to-eat stone crab claws to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders your seafood products adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly your cooked stone crab claws are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 through links in FDA's home page at http://www.fda.gov.

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However your firm's HACCP plan for cooked stone crab claws fails to include a critical control point at Receiving to control the food safety hazard of pathogen growth and toxin formation for receipt of cooked claws. Your firm has routinely received cooked crab claws from other sources in the past. Given this history, you must list a critical control point at your Receiving step to ensure that the cooked crab claws have been adequately chilled during transport and delivery.

Additionally, your firm's HACCP plan for cooked stone crab claws does not list cooling and processing critical control points. A review of your monitoring record shows that your firm currently monitors the cooling and processing times for your cooked crab claws. FDA suggests you incorporate these established procedures into your HACCP plan. After you have cooled your claws, we recommend you take an internal temperature of a sample of the product to ensure that the claws have been chilled to below 140°F. That temperature should be recorded as part of your monitoring records. Since it appears that you are cooling your crab claws to a temperature where they can be handled for packing (e.g. above 70°F) and you can assume that the temperature of the processing area lacking air conditioning will normally exceed 70°F, FDA recommends that the total exposure time during sorting, weighing, and packing not exceed 2 hours. If you assume your processing room's temperature is above 70°F, you do not need to monitor the ambient temperature. Page 156 of the Fish and Fisheries Products Hazards and Controls Guidance can help you determine what limits are appropriate for your process. FDA also suggests that during packing the product be surrounded with ice, not just placing ice on the top of the bagged product.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures and frequencies for each critical control point to ensure compliance with critical limits, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plans for "Cooked Stone Crab Claws" lists a monitoring frequency, "Daily," at the Cooler Storage CCP that is not adequate to control pathogen growth and toxin formation. Your monitoring records indicate that you are monitoring your cooler temperature. FDA recommends you do so by means of a continuous temperature monitoring device, such as a temperature data logger or a high temperature alarm to ensure that safe temperatures are maintained at all times. Alternatively, if you choose to monitor the adequacy of the ice that surrounds your packed product (as listed in your plan), FDA suggests visual checks of a representative number of cases at least twice a day.

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas of sanitation with sufficient frequency to ensure, at a minimum, conformance with conditions and practices specified in 21 CFR Part 110 as follows:

    a. Your firm failed to adequately monitor the safety of water that contacts food and food contact surfaces as evidenced by water hoses in the production area lacking antisiphonage devices.

    b. Your firm failed to monitor the condition and cleanliness of food contact surfaces as evidenced by the accumulation of residues from previous production on the grading table, scale, and scale platform.

    c. Your firm failed to adequately monitor the prevention of cross-contamination from insanitary objects to food as evidenced by the observation of employees handling raw fish and crabs and

then handling cooked crab claws without washing or sanitizing their hands and the presence of hose ends in direct contact with the floor.

d. Your firm failed to protect food and food packaging material from adulteration with contaminants as evidenced by the lighting fixtures lacking protective shields in the cooking room and grading room; employees drinking and smoking in the processing area; and the presence of an employee without a hair restraint packing exposed ready-to-eat stone crab claws.

e. Your firm failed to adequately exclude pests from the food plant as evidenced by the presence of live flies in the processing areas.

You should be aware that our investigator observed that you had documented information regarding sanitation conditions in your sanitation records that did not represent the actual conditions in the plant. Your records indicated that on 5/7/2002 your food contact surfaces were clean. However, our investigator observed the surfaces were in fact encrusted with residues during his inspection on that same day. Sanitation monitoring records are a requirement of 21 CFR 123 (Seafood HACCP Regulation) and therefore, fall within the jurisdiction of FDA. All observations noted on required HACCP documents must be factual and recorded at the time of observation.

In addition, your firm's established HACCP plan lists two critical control points (CCPs) at Cooking. These CCPs list different critical limits and monitoring procedures. We suggest you review and revise your HACCP plan to establish one CCP at Cooking with the critical limits and monitoring procedures reflective of your firm's current operations.

We acknowledge your statements during our inspection promising discontinuance of receiving cooked claws and promising corrective action. However, we have not received any written response addressing these corrections. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, sanitation records and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

Sincerely,

Emma R. Singleton
Director, Florida District